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Safety and effectiveness of the Genous™ endothelial progenitor cell-capture stent in the first year following ST-elevation acute myocardial infarction: A single center experience and review of the literature[☆]

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ABSTRACT

Purpose: The Genous™ stent (GS) is designed to accelerate endothelialization, which is potentially useful in the pro-thrombotic environment of ST-elevation acute myocardial infarction (STEMI). We aimed to evaluate the safety and effectiveness of the GS in the first year following primary percutaneous coronary intervention (PCI) and to compare our results with the few previously published studies.

Methods and Materials: All patients admitted to a single center due to STEMI that underwent primary PCI using exclusively GS, between May 2006 and January 2012, were enrolled. The primary study endpoints were major adverse cardiac events (MACEs), defined as the composite of cardiac death, acute myocardial infarction and target vessel revascularization, at one and 12 months.

Results: In the cohort of 109 patients (73.4% male, 59 ± 12 years), 24.8% were diabetic. PCI was performed in 116 lesions with angiographic success in 99.1%, using 148 GS with median diameter of 3.00 mm (2.50–4.00) and median length of 15 mm (9–33). Cumulative MACEs were 2.8% at one month and 6.4% at 12 months. Three stent thromboses (2.8%), all subacute, and one stent restenosis (0.9%) occurred. These accounted for the four target vessel revascularizations (3.7%). At 12 months, 33.9% of patients were not on dual antiplatelet therapy.

Conclusions: GS was safe and effective in the first year following primary PCI in STEMI, with an apparently safer profile comparing with the previously published data.

Summary: We report the safety and effectiveness of the Genous™ stent (GS) in the first year following primary percutaneous coronary intervention in ST-elevation acute myocardial infarction. A comprehensive review of the few studies that have been published on this subject was included and some suggest a less safe profile of the GS. Our results and the critical review included may add information and reinforce the safety and effectiveness of the GS in ST-elevation in acute myocardial infarction.

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1. Introduction

The Genous™ bio-engineered R stent™ (GS) (OrbusNeich, Fort Lauderdale, Florida), is covered by monoclonal CD34⁺ antibodies that selectively capture the circulating endothelial progenitor cells, which accelerate the healing of the stented lesion [1,2]. Usage of the GS specifically in ST-elevation acute myocardial infarction (STEMI) may offer great benefit in a highly pro-thrombotic environment, potentially reducing stent thrombosis [3,4]. On the other hand, patient

adherence to dual antiplatelet therapy (DAPT) following acute myocardial infarction is suboptimal [5] and the GS could minimize the consequences of early DAPT discontinuation [6]. Few studies have been published on the safety and effectiveness of the GS use exclusively in STEMI patients [7–13]. Different results have been reported and a less safe profile of the GS has been suggested in some of these studies [7,8,13].

We aimed to evaluate the safety and effectiveness of the GS in the first year following primary percutaneous coronary intervention (PCI) in STEMI. We also reviewed the clinical results of the published studies on the GS usage that only included STEMI patients.

2. Methods

2.1. Patients and data collection

We conducted a cohort study of all STEMI patients admitted to our center treated with primary PCI using exclusively GS, between May

Abbreviations: DAPT, dual antiplatelet therapy; GS, Genous™ stent; MACE, major adverse cardiac event; PCI, percutaneous coronary intervention; STEMI, ST-elevation acute myocardial infarction; TIMI, thrombolysis in myocardial infarction; TLR, target lesion revascularization; TVR, target vessel revascularization.

[☆] There are no conflicts of interest to declare.

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2006 and January 2012. The study protocol was approved by the hospital ethics committee and all patients signed informed consent forms before primary PCI.

In our center, the STEMI patients with barriers to prolonged dual antiplatelet therapy (DAPT) were selected to receive a Genous™ stent (GS) during the study period. The barriers included low patient adherence to the treatment regimen, the need to interrupt antiplatelet therapy due to non-cardiac invasive procedures or an increased hemorrhagic risk (mainly due to concomitant need for oral anticoagulation or recent bleeding). We analyzed the STEMI patients that received exclusively the GS.

Based on the clinical files, the following data were recorded: demographic and clinical data, including cardiovascular risk factors, previous cardiovascular events and other comorbidities; angiographic and PCI procedural data; and inhospital clinical and angiographic complications.

A clinical follow-up at one month and 12 months after discharge was carried out based on clinic visits or phone enquiry, and the following data were accounted for and verified by hospital records: death, acute myocardial infarction, target vessel revascularization (TVR), target lesion revascularization (TLR), clinical stent restenosis, stent thrombosis, angina or anginal equivalent and DAPT discontinuation.

Usage of a stent other than Genous™, rescue PCI and PCI performed after the first 12 h of the beginning of the symptoms were the exclusion criteria.

2.2. Endpoints

The primary study endpoints were major adverse cardiac events (MACEs), defined as the composite of cardiac death, acute myocardial infarction and target vessel revascularization, at one and 12 months. The incidence of stent thrombosis and clinical stent restenosis was also assessed.

2.3. Definitions

All deaths were considered a cardiac death unless otherwise documented. Acute myocardial infarction was defined according to Academic Research Consortium definition [14] as elevation of cardiac enzymes 3 times the upper limit of normal. TVR was defined as repeat revascularization of the previously treated vessel, and TLR as repeat revascularization within 5 mm to stent edges (in-segment). Clinical stent restenosis was defined as the presence of angina or anginal equivalent, associated with >50% stenosis in the segment covered by the stent or the adjacent 5 mm. Stent thrombosis was classified according to Academic Research Consortium definitions [14] in which definite stent thrombosis is defined as angiographic or pathologic confirmation of acute stent thrombosis in patients with acute coronary syndromes; and probable stent thrombosis as any unexplained death in the 30 days following stent implantation or as target vessel myocardial infarction without angiographic confirmation of stent thrombosis or other identified culprit lesion. Stent thrombosis was classified as acute (first 24 h), subacute (between 24 h and 30 days) and late (after 30 days). Angiographic success was defined as residual stenosis of less than 10% and thrombolysis in myocardial infarction (TIMI) flow score 3.

2.4. Review of the published data

We searched the studies in full version indexed in the Pubmed®, between January 2005 (GS first-in-man [15]) and May 2013, using the keywords endothelial progenitor cell, Genous™ stent, myocardial infarction, percutaneous coronary intervention, and stent. Of the studies reporting GS usage, only those that enrolled exclusively STEMI

Table 1

Demographic and clinical data.

	N = 109	%
Male	80	73.4
Hypertension	61	56.0
Dyslipidemia	58	53.2
Smoking history	58	53.2
Diabetes mellitus	27	24.8
Obesity	19	17.4
Previous acute myocardial infarction	7	6.4
Previous percutaneous coronary intervention	3	2.8
Previous coronary artery bypass grafting	0	0.0
Pre-discharge depressed left ventricular ejection fraction (<55%)	51	46.8

patients were analyzed. Time of follow-up, the number of GS used, the number of patients included, intended DAPT duration, MACE, cardiac death, acute myocardial infarction, TVR, TLR, stent restenosis and stent thrombosis were analyzed.

2.5. Statistical analysis

Data were analyzed using the SPSS version 17.0 statistical software. Discrete data are presented as frequencies and percentages, whereas continuous variables are presented as means and SD or as medians and range, when appropriate.

3. Results

Nine hundred and seventy (970) STEMI patients were treated with primary PCI in our center during the study period. Of these, 115 patients received a GS since they had barriers to prolonged DAPT, but six were excluded since they received another type of stent in addition to the GS. In our cohort of 109 patients, 80 (73.4%) were male and the mean age was 59 ± 12 years. Demographic and clinical data are presented in Table 1. One quarter of the patients had diabetes mellitus on medication.

Angiographic data are presented in Table 2. In 102 (93.6%) patients only the culprit artery was treated and PCI was performed in 116 lesions. Of the intervened lesions, 49 (42.2%) were located in the left anterior descending artery, 78 (67.2%) were type B2/C and the mean stenosis was $95.6 \pm 12.0\%$.

Procedural data are presented in Table 3. Angiographic success was achieved in 115 (99.1%) PCIs. One hundred and forty eight GSs were used with a median diameter of 3.00 mm (2.50–4.00 mm) and a median length of 15 mm (9–33 mm). Anticoagulant and antiplatelet

Table 2

Angiographic data.

	N = 109	%
Multivessel disease	37	33.9
Lesions treated per patient		
1	102	93.6
>1	7	6.4
Intervened lesion	N = 116	%
Left anterior descending artery	49	42.2
Right coronary artery	47	40.5
Circumflex artery	19	16.4
Left main artery	1	0.9
Lesion risk profile	N = 116	%
Lesion type B2/C	78	67.2
Long lesion	34	29.3
Bifurcation lesion	13	11.2
Calcified lesion	4	3.4
Thrombotic lesion	69	59.5
Previous stenting (another stent)	2	1.7

Table 3
Procedural data.

	Pre-intervention	Post-intervention
TIMI flow score	N = 116 (%)	N = 116 (%)
0	68 (58.6)	0 (0.0)
1	10 (8.6)	0 (0.0)
2	5 (4.3)	1 (0.9)
3	33 (28.4)	115 (99.1)
	N = 109	%
Number of stents per patient		
1	75	68.8
>1	34	31.2
Glycoprotein IIb/IIIa inhibitors (abciximab or tirofiban)	76	69.7
Thrombus aspiration	18	16.5

TIMI: thrombolysis in myocardial infarction.

therapy followed the standard practices [16] and intended DAPT duration was 12 months, for all patients.

3.1. Follow-up

Follow-up was achieved in all of the patients in this cohort. The cumulative event rates during hospitalization, at one month and 12 months after PCI are presented in Table 4. The mean DAPT duration was 9.8 ± 3.5 months and the clinical events that occurred under DAPT and after DAPT discontinuation are presented in Table 4.

During hospitalization, one stent thrombosis occurred 48 h after PCI (subacute). Thrombus aspiration and balloon angioplasty were performed with success and the patient survived the recurrent myocardial infarction. There was no acute stent thrombosis.

Between discharge and one month follow-up, two reinfarctions were documented, both due to subacute GS thrombosis. One occurred 11 days after PCI and the patient was on 100 mg aspirin plus 75 mg clopidogrel per day, despite weighting 141 kg. The other stent thrombosis occurred 21 days after PCI and the patient had discontinued DAPT since discharge, against medical advice. In both patients PCI was performed with success and both survived. At the end of the first month (107 patients alive), 6.5% of patients were not on DAPT.

Table 4
Cumulative events at in-hospital, 1 month, 12 months, under DAPT and after DAPT discontinuation.

Period of follow-up	In-hospital		1 month		12 months		Under DAPT 9.8 \pm 3.5 months		After DAPT discontinuation 2.2 \pm 3.5 months	
	N	%	N	%	N	%	N	%	N	%
Patients	109	100	109	100	109	100	72	66.1	37	33.9
MACE	1	0.9	3	2.8	7	6.4	4	5.6	3	8.1
Death	2	1.8	2	1.8	10	9.2	7	9.7	3	8.1
Cardiac	0	0.0	0	0.0	3	2.8	2	2.8	1	2.7
Non-cardiac	2	1.8	2	1.8	7	6.4	5	6.9	2	5.4
Acute myocardial infarction	1	0.9	3	2.8	4	3.7	3	4.2	1	2.7
TVR/TLR ^a	1	0.9	3	2.8	4	3.7	4	5.6	0	0.0
CABG	0	0.0	0	0.0	1	0.9	1	1.4	0	0.0
PCI	1	0.9	3	2.8	3	2.8	3	4.2	0	0.0
Clinical stent restenosis	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0
Stent thrombosis	1	0.9	3	2.8	3	2.8	2	2.8	1	2.7
Definite	1	0.9	3	2.8	3	2.8	2	2.8	1	2.7
Probable	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Acute	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Subacute	1	0.9	3	2.8	3	2.8	2	2.8	1	2.7
Late	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

CABG: coronary artery bypass grafting; DAPT: dual antiplatelet therapy; MACE: major adverse cardiac event; PCI: percutaneous coronary intervention; TLR: target lesion revascularization; TVR: target vessel revascularization.

^a All the TVRs were TLRs.

Between one and 12 months follow-up, three cardiac deaths occurred: an acutely decompensated heart failure (month 6), a reinfarction unrelated to the culprit lesion at the index event (month 7), and a sudden unexplained death (month 7). There was one stent restenosis presenting as an acute coronary syndrome seven months after PCI. Disease progression to triple vessel disease (including restenosis of the GS) was documented and surgical revascularization was performed. No late stent thrombosis was documented. At the end of 12 months (99 patients alive), 33.9% of patients were not on DAPT.

4. Discussion

Usage of the GS specifically in STEMI may be an important alternative since it may reduce stent thrombosis in a highly pro-thrombotic environment [3,4]. It may also minimize the consequences of early DAPT discontinuation [6]. STEMI patients with barriers to DAPT were selected to receive the GS in our center and this study evaluated the 12-month safety and effectiveness of the GS following primary PCI in a cohort of 109 patients. The GS had a good performance, probably related to the rapid endothelialization [17]. MACE, cardiac death, TVR/TLR, clinical stent restenosis and stent thrombosis rates were low despite frequent early DAPT discontinuation.

About one third of patients were not on DAPT at 12 months following the acute coronary syndrome. In addition, some patients may have transiently interrupted DAPT for non-cardiac invasive procedures, thus increasing the thrombotic risk. The use of other type of stents might have been associated with a higher stent thrombosis rate in these patients [18].

4.1. Review of the published data

Table 5 summarizes the clinical results of the few published studies that included patients treated with the GS exclusively in STEMI and includes our results as well. Data are expressed as cumulative events at the end of the follow-up period and are presented according to the definitions used in our study. The studies by Bystroň et al [7], and Co et al [9], are exceptions, since cardiovascular death (including stroke) is presented instead of cardiac

Table 5

Studies on GS use exclusively in STEMI (cumulative events at the end of follow-up).

	Bystroň M [7].	Scacciatella P [8].	Co M [9].	Present study	Lee Y [10].	Santas-Alvarez [11]	Chong E [12].	Low A [13].
FUP (months)	6	6	12	12	12	18 (mean)	24	34 (mean)
# GS	60	74	129	148	357	177	106	104
# Patients	50	50	120	109	321	139	95	95
Intended DAPT (months)	1	1	1	12	1	12	1	1
MACE (%)	24.0	18.0	9.2	6.4	12.2	–	13.7	15.8
Cardiovascular death ^a /cardiac death ^b (%)	4.0 ^a	2.0 ^b	3.3 ^a	2.8 ^b	5.9 ^b	2.9 ^b	9.5 ^b	0.0 ^b
Acute myocardial infarction (%)	–	4.0	2.5	3.7	2.2	–	1.1	2.1
TLR ^c /TVR ^d (%)	14.0 ^c	10.0 ^c / 12.0 ^d	5.8 ^{c,d}	3.7 ^{c,d}	4.1 ^c / 4.4 ^d	3.8 ^c / 5.8 ^d	4.2 ^d	–
SR ± symptoms ^e /clinical SR ^f (%)	18.0 ^e	–	4.2 ^f	0.9 ^f	–	5.0 ^f	–	28.4 ^e (8 mo)
ST (%)	6.0	0	1.7	2.8	0.9	1.4	1.1	0.0
Acute ST (%)	0.0	0	0.8	0.0	0.3	0.7 (inhospital)	1.1	0.0
Subacute ST (%)	2.0	0	0.8	2.8	0.6	–	0	0.0
Late ST (%)	4.0	0	0.0	0.0	0.0	0.7	0	0.0

DAPT: dual antiplatelet therapy; FUP: follow-up period; GS: Genous™ stent; MACE: major adverse cardiac events; SR: stent restenosis; ST: stent thrombosis; TLR: target lesion revascularization; TVR: target vessel revascularization. Superscript a to f – outcomes considered in the original studies.

death and MACE includes cardiovascular death instead of cardiac death. In addition, for the study by Bystroň et al [7], TLR is presented instead of TVR and MACE includes TLR instead of TVR. Of note, some studies [9,10,12,13] were conducted in the same hospitals in coincident periods, thus some patients may have been included in different studies.

Some studies suggest that the GS might not be safe in STEMI patients, as the rates of clinical complications were high, particularly regarding MACE [7,8,13]. Methodological differences may account for some of these results. The studies by Bystroň et al [7], and Low et al [13], reported high rates of stent restenosis. Only on these studies, an angiographic follow-up was performed, which may have increased the detection of angiographically significant but asymptomatic stent restenosis, thus increasing repeat revascularization and MACE rates. In the study by Scacciatella et al [8], a single-photon emission computed tomography was routinely performed at 6-month follow-up (results not available) which may have increased the detection of asymptomatic stent restenosis and also increased the rates of TVR and MACE. In addition, the 34% multivessel PCI rate was high, which may have added to the TVR rate. The study by Bystroň et al [7], reported a higher rate of stent thrombosis (6.0%) in comparison to any of the other studies, where stent thrombosis ranged from 0.0% to 2.8% (in our cohort), and the results of Bystroň et al. may be an outlier. Finally, the studies by Bystroň et al [7], and Scacciatella et al [8], analyzed only small samples (50 patients).

Although the rates of the events cannot be directly compared between the different studies due to methodological differences, in our cohort the GS seemed to show a safer profile in comparison with most studies – the rates of MACE, death, TVR/TLR and clinical stent restenosis were numerically lower. Differences in clinical and angiographic characteristics of the populations may account for some of these differences, and possibly our cohort included lower risk patients. The routine revaluation by coronary angiography or single-photon emission computed tomography may also explain higher event rates in some studies. In our study, the rate of multivessel PCI was low (6.4%), while a multivessel PCI rate up to 34% has been reported [8], which may have added to the TVR and MACE rates in the latter. In addition, the intended DAPT duration was 12 months in our study, and in most other studies it was 1 month; this may have decreased the event rates in our cohort.

The stent thrombosis rate in our cohort was not lower than in most studies [8–13]. The three cases of definite stent thrombosis in our study were subacute: the first occurred early (48 h after PCI) without any apparent stent abnormality in the following angiography; the second was probably due to relative antiplatelet underdosing, considering the overweight; the third was probably related to early

DAPT discontinuation. Acute stent thrombosis has been reported [9,10,12] but none occurred in our patients. Late stent thrombosis, a concern with drug eluting stents [19], was not documented in our patients and only two of the analyzed studies have reported late thrombosis with GS after STEMI [7,11] (Table 5).

4.2. Limitations

This study has the limitations of being a single center study, including a small sample and reporting only clinical follow-up at one year with no systematic angiographic revaluation. However, given the lack of large studies on GS use in STEMI and the heterogeneity of data in previous studies, our results and the review of the literature may add information and reinforce the safety and effectiveness of the GS in STEMI. Larger randomized studies are needed to confirm safety and efficacy of the endothelial progenitor cell capturing technology.

5. Conclusions

The GS was safe and effective in the first year following primary PCI in STEMI patients, despite high rates of early DAPT discontinuation. In our cohort the GS seemed to reveal a safer profile in comparison with most previous studies. These results reinforce the GS as a good option in STEMI patients.

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